

Public Hearings

EFPIA is fully supportive of openness and transparency

- To engage the spectrum of stakeholders affected by the safety of medicines,
- To promote understanding and trust of the public, patients and healthcare professionals.

EFPIA appreciates clarification in Directive 2010/84/EU that public hearings should only take place “on justified grounds” and “due regard shall be given to the therapeutic effect of the medicinal product”

Further need for clarification

- **Clear criteria what constitutes justified grounds should be made available**
- **The Marketing Authorization Holder(s) concerned should be significant contributors at these meetings**
- **Information about upcoming public hearings should be timely and allow for sufficient preparation**